



NIH BACKGROUNDER

National Institutes of Health

Re-engineering the Clinical Research Enterprise

Clinical research is the linchpin of the nation's biomedical research enterprise. Before a therapy is approved for general use, it must be studied carefully in the laboratory to understand how the treatment works, how effective it is, and what potential risks may exist. The safety and benefits of the therapy for humans must then be proven through an orderly series of tests in people. Over the years, medical research has succeeded in converting many diseases once considered uniformly lethal into more chronic, treatable conditions. Yet clinical research has become increasingly difficult to do and it has become clear to the scientific community that the United States must recast its entire system of clinical research if such efforts are to remain as successful as they have been in the past.

To accelerate and strengthen the clinical research process, a set of NIH Roadmap initiatives will work toward improving the clinical research enterprise by adopting a systematic infrastructure that will better serve the evolving field of scientific discovery. This effort, which complements the other initiatives that comprise the NIH Roadmap, will provide the necessary foundation for advancing basic and clinical research. With the NIH Roadmap in action, investigators will be better poised to translate basic discoveries into the reality of better health for our nation. Several initiatives are in place to carry forward this goal:

- Clinical Research Networks and NECTAR
- Clinical Research Policy Analysis and Coordination
- Clinical Research Workforce Training
- Dynamic Assessment of Patient-Reported Chronic Disease Outcomes
- Translational Research

The speed at which exciting basic science discoveries emerge from laboratories demands that clinical research continue and even expand, while at the same time be more efficient and better inform basic science efforts. This is undoubtedly the most difficult but most important challenge identified by the NIH Roadmap process.

At the core of this vision is the concept that clinical research needs to develop new partnerships among organized patient communities, community-based health care providers, and academic researchers. In the past, all research for a clinical trial could be conducted in one academic center; that is unlikely to be true in the future. In the Re-engineering the Clinical Research Enterprise Roadmap initiatives, NIH will promote the creation of better integrated networks of

academic centers that work jointly on clinical trials and that include community-based health care providers who care for sufficiently large groups of well-characterized patients.

Implementing this vision will require new ways to organize the way clinical research information is recorded, new standards for clinical research protocols, modern information technology, new models of cooperation between NIH and patient advocacy alliances, and new strategies to strengthen the clinical research workforce.

The URL for the NIH Roadmap web site is nihroadmap.nih.gov. For more information on the Re-Engineering the Clinical Research Enterprise initiatives, please consult the individual Roadmap Web pages describing each area. Further information about NIH can be found at its Web site: www.nih.gov.